

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: E. Altmann

Art Unit: 1624

Examiner: V. Balasubramanian

APPLICATION NO: 10/525,658

PATENT NO: 7544688

FILED: August 23, 2005

FOR: HETEROARYL NITRILE DERIVATIVES

MS: General

Commissioner for Patents

PO Box 1450

Alexandria, VA 22313-1450

PETITION REGARDING PATENT TERM ADJUSTMENT POST GRANT UNDER C.F.R. §1.705(d)

Sir:

In accordance with 37 C.F.R. § 1.705(d), Applicant hereby applies for patent term adjustment under 35 U.S.C. § 154(b) of 385 days. This application is being filed within two months of the date the patent issued, as required by 37 C.F.R. § 1.705 (d).

As an initial matter, Applicants appreciate the information provided in the Office of Petitions letter dated April 16, 2009 regarding the preliminary petition for patent term adjustment filed March 6, 2009. A copy of the letter is enclosed herewith.

I. Fee

The Office acknowledged receipt of the petition fee of \$200.00 required by 37 C.F.R. §1.705(b)(1) in the letter dated April 16, 2009. The letter further indicated that no additional fees are required for consideration of the instant petition. Please charge any deficiencies or any additional fees due in response to this request to Deposit Account 50-4409.

II. Statement of the Facts Involved

A. Correct Patent Term Adjustment

The Notice of Allowance, which was mailed on December 16, 2008, indicated a preliminary Patent Term Adjustment of 518 days.

Patentee has calculated an final patent term adjustment of 808 days based on the following facts:

Case Law

In *Wyeth v. Dudas*, 2008 U.S. Dist. LEXIS 76063 (D.D.C. 2008), the District Court of the District of Columbia addressed the United States Patent and Trademark Office (USPTO) interpretation of 35 U.S.C. § 154(b)(2). The Court granted summary judgment in favor of Wyeth, determining that the USPTO misconstrued the first sentence of 35 U.S.C. § 154(b)(2)(A), and as a result, improperly denied Wyeth a portion of patent term to which Wyeth was entitled under 35 U.S.C. § 154.

In the opinion, the Court stated that "the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for 'A delay' or for 'B delay,' whichever is larger, but never A + B." However, Plaintiff Wyeth argued that the § 154(b)(1)(A) and § 154(b)(1)(B) period overlap only if they occur on the same calendar day or days. The Court determined that Wyeth's construction of § 154(b)(2)(B) was correct.

Simply put, the holding of the Court is that the excluded overlap recited in the first sentence of 35 U.S.C. § 154(b)(2)(A) only occurs if a 35 U.S.C. § 154(b)(2)(A) period and a 35 U.S.C. § 154(b)(2)(B) period run concurrently. As such, a patent holder is entitled to recoup the 35 U.S.C. § 154(b)(2)(A) period that falls outside of the 35 U.S.C. § 154(b)(2)(B) period in addition to the 35 U.S.C. § 154(b)(2)(B) period itself.

Relevant Dates

The above identified application has a 35 U.S.C. §371 filing date of August 23, 2005.

The first Office Action, which was a Restriction Requirement, was mailed on March 24, 2008, resulting in a PTO delay of 518 days beyond the 14 months provided by 35 U.S.C. §154(b).

A Response by Patentee was filed April 22, 2008, within the 3 months provided by 35 U.S.C. §154(b).

An Office Action was mailed June 24, 2008, within the 4 months provided by 35 U.S.C. §154(b).

A Response by Patentee was filed September 22, 2008, within the 3 months provided by 35 U.S.C. §154(b).

A Notice of Allowance was mailed December 16, 2008, within the 4 months provided by 35 U.S.C. §154(b).

The issue fee has been paid on March 6, 2009 in a paper accompanying the instant petition, within the 3 months provided by 35 U.S.C. §154(b).

Accordingly, the initial PTO adjustment based on delay under 35 U.S.C. § 154(b)(2)(A) is 518 days. The reduction in term adjustment due to applicant delay is 0 days, resulting in a patent term adjustment of 518 days under 35 U.S.C. § 154(b)(2)(A).

The 35 U.S.C. § 154(b)(2)(B) period for the instant application began on August 23, 2008 (three years after the filing date of August 23, 2005) and ended on June 9, 2009 with the issuance of the instant application. The 35 U.S.C. § 154(b)(2)(B) period is 290 days. The reduction in term adjustment due to applicant delay is 0 days, resulting in an initial patent term adjustment of 290 days under 35 U.S.C. § 154(b)(2)(B).

There was 0 days of PTO delay under 35 U.S.C. § 154(b)(2)(A) that occurred within the 35 U.S.C. § 154(b)(2)(B) period that should be excluded from the patent term adjustment calculation under the holding of *Wyeth v. Dudas*.

Accordingly, the sum of the 35 U.S.C. § 154(b)(2)(B) delay (290 days) and non-overlapping 35 U.S.C. § 154(b)(2)(A) delay (518 days) is 808 days.

The initial PTA printed on the Issue Notification is only 518 days, which the USPTO is presumed to have calculated using the method considered proper before the holding of *Wyeth v. Dudas*. Applicants therefore respectfully request reconsideration of the initial PTA calculation.

B. Terminal Disclaimer


The above-identified patent is not subject to a Terminal Disclaimer.

C. Reasonable Efforts

Any applicant delays under 37 C.F.R. § 1.704 are set forth above. There were no other circumstances constituting a failure to engage in reasonable efforts to conclude processing of examination of the above-identified application, as set forth in 37 C.F.R. § 1.704.

Novartis Institutes for BioMedical Research, Inc.
220 Massachusetts Avenue
Cambridge, MA 02139
(617) 871-3105

Respectfully submitted,



John Alexander
Attorney for Applicant
Reg. No. 48,399

Date: August 3, 2009